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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/347,175	07/01/1999	JAMES M. HOGLE	HU98-02PA	3518

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EXAMINER

ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 05/12/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/347,175

Applicant(s)

HOGLE ET AL.

Examiner

Robert A. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10,17-19,41-44 and 58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,4-6 and 58 is/are allowed.
- 6) ☒ Claim(s) 7-10,17-19 and 41-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

The amendment and response filed on 3-10-2003 is acknowledged. Claims 1, 17-19 and 41-44 have been amended. Claims 11-16, 20-40 and 45-57 have been canceled. Claims 1-2, 4-10, 17-19, 41-44 and 58 are pending and currently under examination.

#### ***Claim Objections Withdrawn***

The objection to claim 1 for containing an obvious typographical error is withdrawn in light of the amendment thereto.

The objection to claims 16 and 20-21 for starting with the incorrect article is withdrawn. Cancellation of said claims has rendered the objection moot.

#### ***Claim Objections Maintained***

The objection to claims 42 and 44 to for starting with the incorrect article is maintained. Applicant is correct in his assertion that the articles were confused in the objection. Independent claims should start with the article "A" or "An". Dependent claims should start with the article "The". With regard to claims 42 and 44, use of the article "A" suggests that the independent claim (claim 41) recites multiple methods, which is inaccurate.

#### ***Claim Rejections Withdrawn***

The rejection of claims 17-19 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

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invention (derivatives of various HdAg polypeptides) is withdrawn in light of the amendment thereto.

The rejection of claims 41-45 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention (drawn to methods of enhancing interaction between binding partners comprising contacting HDAG fusion molecules with a second binding moieties) is withdrawn in light of the amendment thereto and the cancellation of claim 45.

The rejection of claims 16 and 20-21 under 35 U.S.C. 112, second paragraph, for reciting non-elected claims is withdrawn. Cancellation of said claims has rendered the rejection moot.

The rejection of claim 17 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "depicted" is withdrawn in light of the amendment thereto.

The rejection of claim 17 under 35 U.S.C. 112, second paragraph, for reciting improper Markush language is withdrawn in light of the amendment thereto.

The rejection of claims 17-19 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "derivative" is withdrawn in light of the amendment thereto.

The rejection of claims 41 and 43 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "interaction" is withdrawn in light of the amendment thereto.

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The rejection of claim 41 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by its failure to recite active method steps is withdrawn in light of the amendment thereto.

The rejection of claim 42 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “presents” is withdrawn in light of the amendment thereto.

The rejection of claim 43 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the term “on surfaces” is withdrawn in light of the amendment thereto.

The rejection of claims 17-19 under 35 U.S.C. 102(b) as being anticipated by Lemon et al. (WO 96/20953) is withdrawn in light of the amendment thereto.

The rejection of claim 17 and 19 under 35 U.S.C. 102(b) as being anticipated by Houghton et al. (EP 0 251 757) is withdrawn in light of the amendment thereto.

The rejection of claim 17 and 19 under 35 U.S.C. 102(b) as being anticipated by Makino et al. (Nature, Vol. 329, pages 343-346, 1987 – IDS-5) is withdrawn in light of amendment thereto.

The rejection of claim 17 and 19 under 35 U.S.C. 102(a) as being anticipated by Dingle et al. (Journal of Virology, Vol. 72 No. 6, pages 4783-4788, 1998 – IDS-5) is withdrawn in light of the amendment thereto.

The rejection of claim 17 - 19 under 35 U.S.C. 102(b) as being anticipated by Imazeki et al. (Journal of Virology, Vol. 64, No. 11, pages 5594-5599) is withdrawn in light of the amendment thereto.

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***Claim Rejections Maintained***

***35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 7-10, 17, 19 and 44 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained for reasons of record.

**Applicant argues:**

1. Allowed claims 1-6 are directed to the coiled oligomers that form the coiled coils of Claim 7.
2. There is no reason that the listed binding moieties utilized for the coiled conformation of the oligomer (claims 1-6) would not be envisioned for the coiled-coil conformation of the oligomer.
3. The description of binding the moiety to the oligomer and the location of the binding has been acknowledged via the allowance of claims 5 and 6.
4. Claims 17 and 19 are not drawn to coiled coils but to sequences which form coiled oligomers and upon contact with similar coiled oligomers for a coiled coil and hence are enabled since claims 1-6 are deemed enabled.
5. The rejection appears to be an attempt by the Examiner to accomplish a de-facto restriction requirement under the guise of a rejection.

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6. The rejected claims are directed to oligomers comprising two or more fusion protein molecules of claim 1 and are therefore allowable.

With regard to points 1-3 and 6, the rejected claims are drawn to “**coiled-coil oligomers**” while the allowed claims are drawn to coiled oligomers. Contrary to Applicant’s assertion, enablement of the latter does not confer enablement to the former. A coiled-coil is a much more complex conformation and hence it is much more unpredictable which binding moieties can be added to a given oligomer and still maintain its coiled-coil conformation. It should be noted that the term “coiled-coil” is being interpreted to read on the conformation of the entire molecule. Said term is vague and indefinite as outlined in the rejection made under 35 U.S.C. 112, second paragraph (see below).

In response to applicant’s argument that the references fail to show certain features of applicant’s invention, it is noted that the features upon which applicant relies (i.e., that the coiled coils are formed by contacting similar coiled oligomers) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

With regard to Point 5, the aforementioned rejection is valid and any correlation to a restriction requirement is purely coincidental. Moreover, since all the pending claims have been searched and examined there is no need for any type of restriction requirement, de-facto or otherwise.

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Therefore, as outlined before the rejected claims are drawn to “**coiled-coil oligomers**” and a method of using said oligomers. Said oligomers comprise at least two fusion molecules wherein said fusion molecules comprise a peptide consisting of amino acids 12-88 of the hepatitis D antigen (HDAg) or a fragment thereof that forms a coiled-coil and at least one binding moiety. The specification discloses that said binding moieties can be cytokines, interferons, interleukins, T cell receptors, Fc receptors, plasminogen activators, MHC, tumor suppressor genes, monoclonal antibodies, fragments of antibodies, drug resistance genes and ion channels (among others). The specification also discloses that the **coiled-coil sequence** is located in the N-terminal third (amino acids 12-60) of the HDAg molecule and that residues 50-60 of said molecule are important in oligomer formation. Finally, the specification discloses that HDAg coiled-coil monomers form octamers. However, the specification is silent on what binding moieties, if any could be fused to said monomers and **maintain a coiled-coil conformation**. The specification is equally silent on what binding moieties, if any, would allow for octamer formation. Additionally, the specification gives no guidance on the techniques to be employed in “binding” said moieties to the HDAg or where on the HDAg molecule said moieties are attached. Consequently, given the lack of guidance and the lack of working examples within the specification, it would be impossible for one skilled in the art to make and/or use the claimed invention without undue experimentation.

It should be noted that contrary to Applicant’s assertion, only claims 1-2, and 4-6 have been allowed. Claim 3 is a previously canceled claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:



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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 7-10, 17, 19 and 44 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "coiled coil" is maintained for reasons of record. Contrary to Applicant's assertion, while the specification does disclose that coiled oligomers can combine to form coiled-coiled oligomers, it is still unclear whether the recitation of said term in the rejected claims is meant to describe a conformational limitation of the oligomer or merely the HdAg portion of said oligomer.

### ***Conclusion***

Claims 1-6 and 58 are allowed.

Claims 7-10, 17-19 and 41-44 are rejected.

It should be noted that with regard to the Interview Summary Record, Applicant was notified that the rejoined claims would be rejected under multiple statutes and as such would result in an Office action. This notification was as per the Examiner's agreement with Applicant. At no time, contrary to Applicant's assertion, did the Examiner agree to provide Applicant with rejections in any other form than an Office action. Said Office action was necessitated by Applicant's desire to have claims rejoined.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991.

The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
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Robert A. Zeman  
May 8, 2003